

# Assessing Animal Models of Bacterial Pneumonia Used in Investigational New Drug Applications for the Treatment of Bacterial Pneumonia

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No disclosures/conflicts of interest

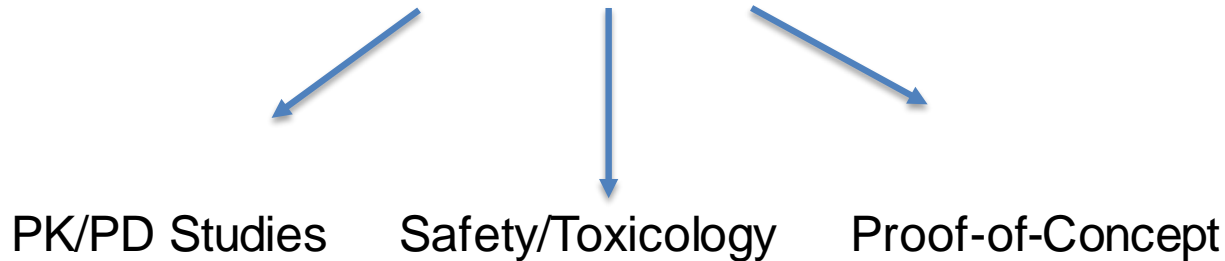
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# Animal Models Used in Early Drug Development



## Nonclinical Development

## Clinical Development



# Development of Databases



## IND Database

INDs submitted to Division of Anti-Infectives  
since Jan. 1, 2000



Search terms: pneumonia or bacterial infection  
*No tuberculosis, cystic fibrosis, or biothreats*

**27 INDs, 180 studies**

## Published Studies Database

Search PubMed with

- “Animal model pneumonia antibacterial”
- January 1, 2000 to December 31, 2019



Literature with pneumonia model

- *No tuberculosis, cystic fibrosis, or biothreats*
- Treatment after bacterial inoculation
- No co-infection with virus (*i.e.* influenzae strain)

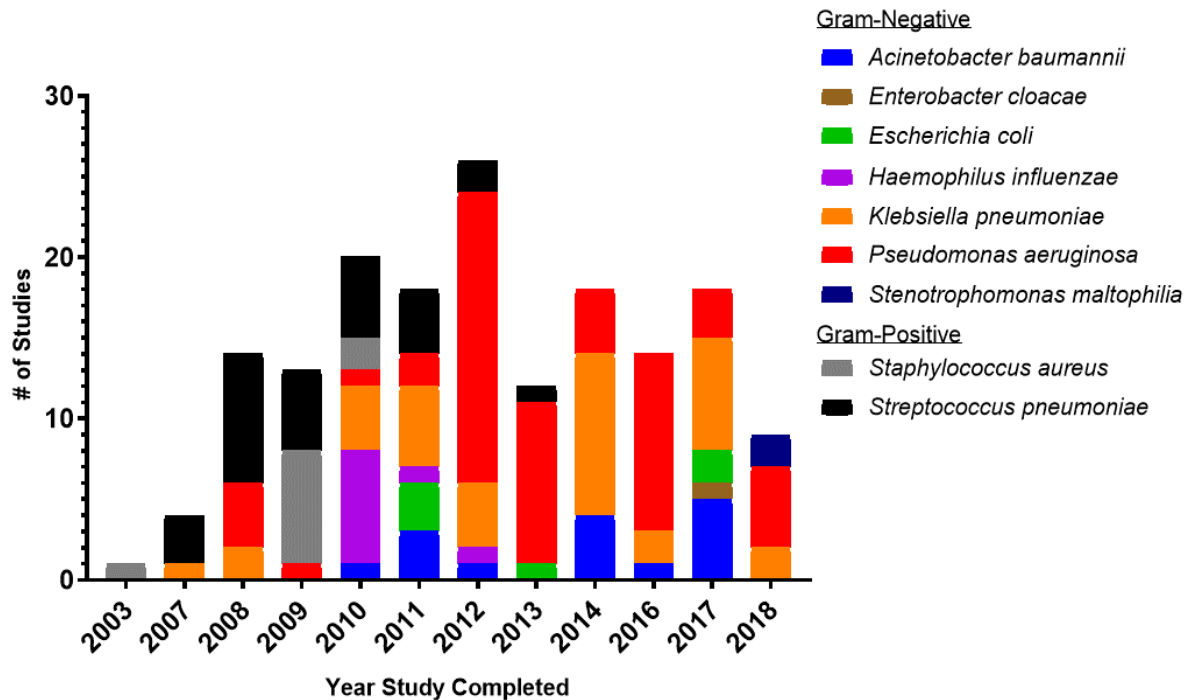


Study not included in IND database

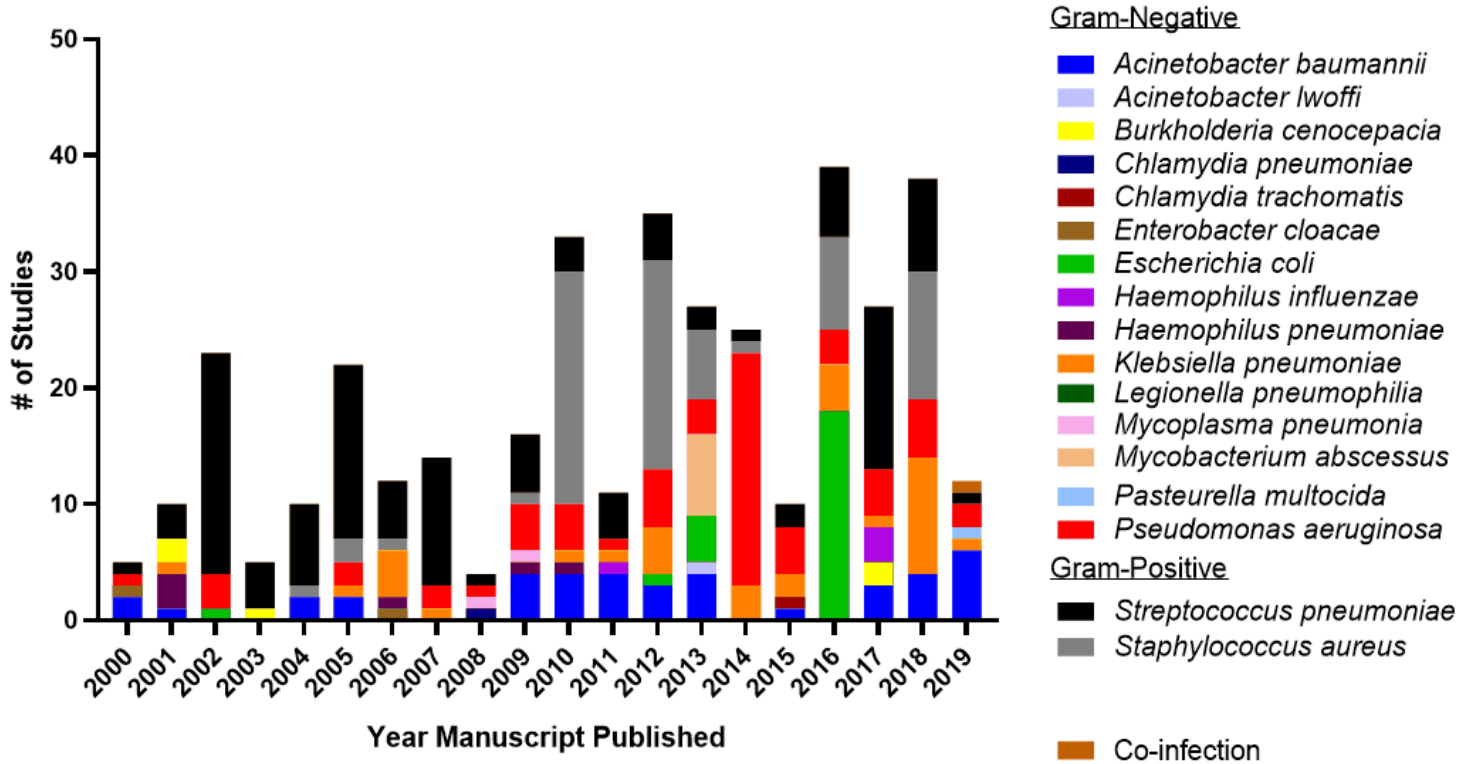
- Removed 22 studies

**137 papers, 377 studies**

# Trend towards using more Gram-Negative bacteria in IND studies



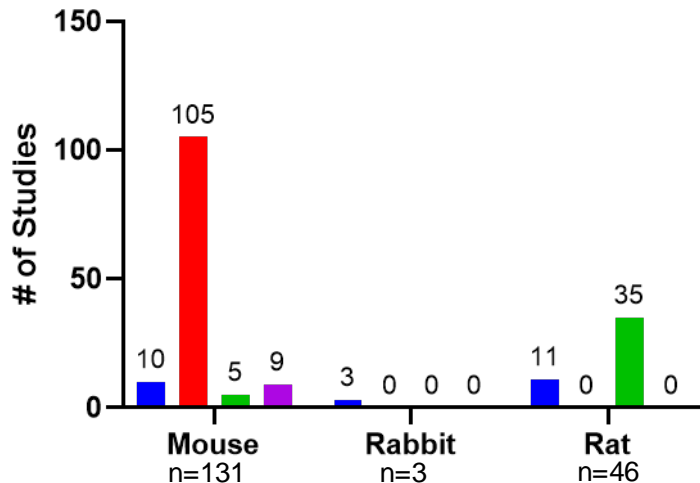
# Bacteria in Published Studies



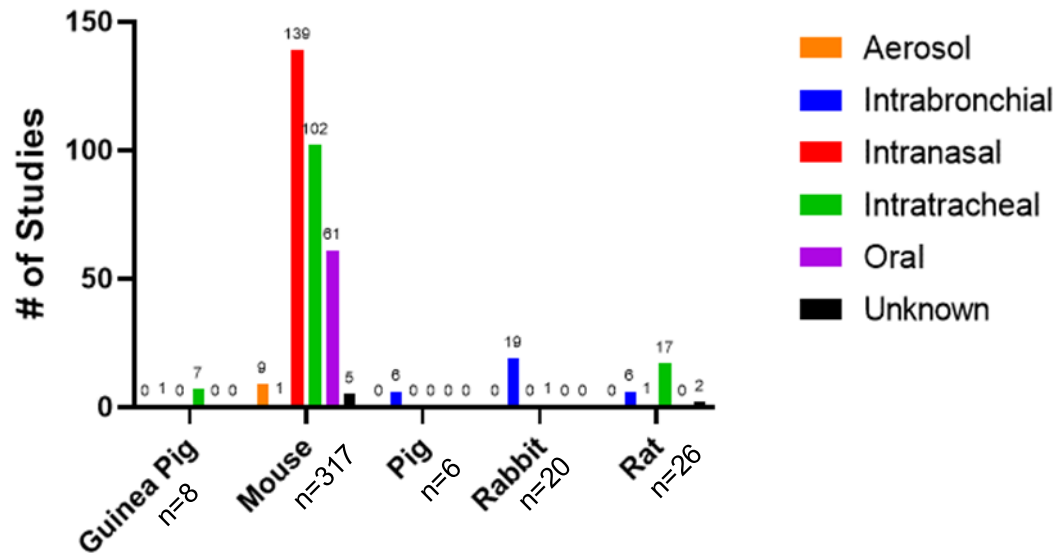
# Murine Models Predominately Used



IND Database (n=180)

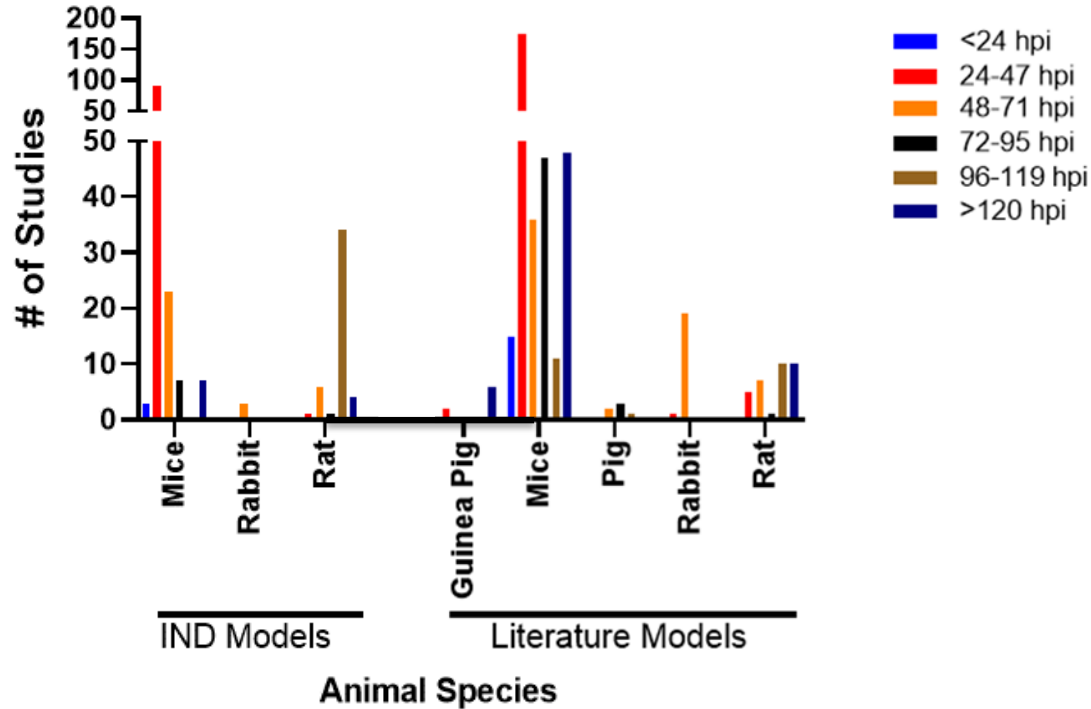


Published Studies Database (n=377)



\*No ventilator-associated pneumonia models in IND database

# Mice used for shorter studies

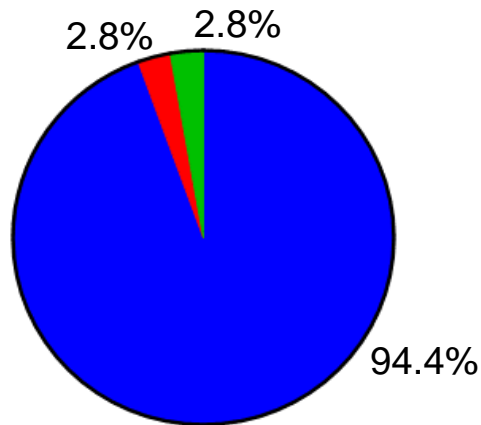




# Bacterial Load Most Common Endpoint

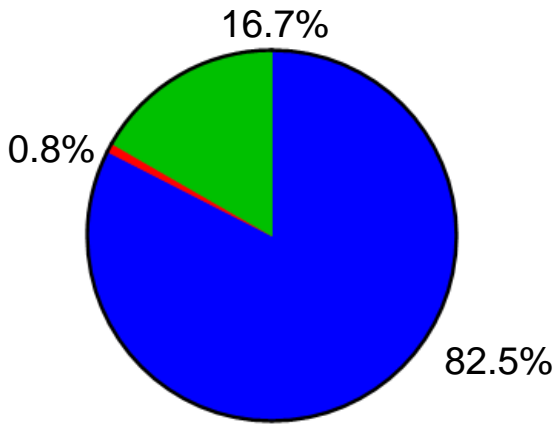


IND Database



Total=180

Published Literature Database



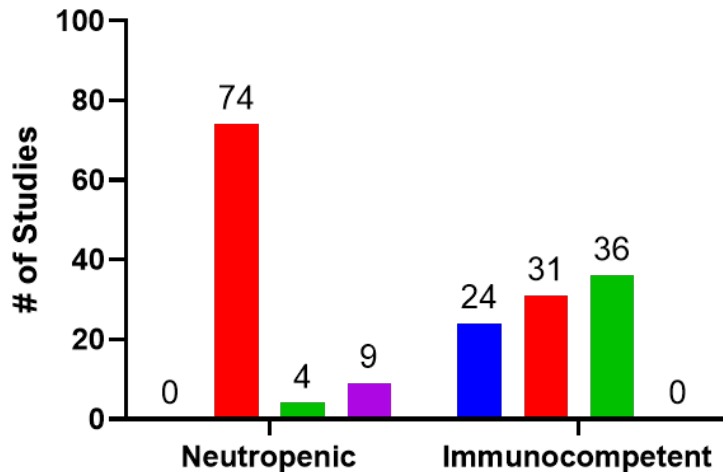
Total=377

- Bacterial Load
- Dose for 50% Survival
- Survival

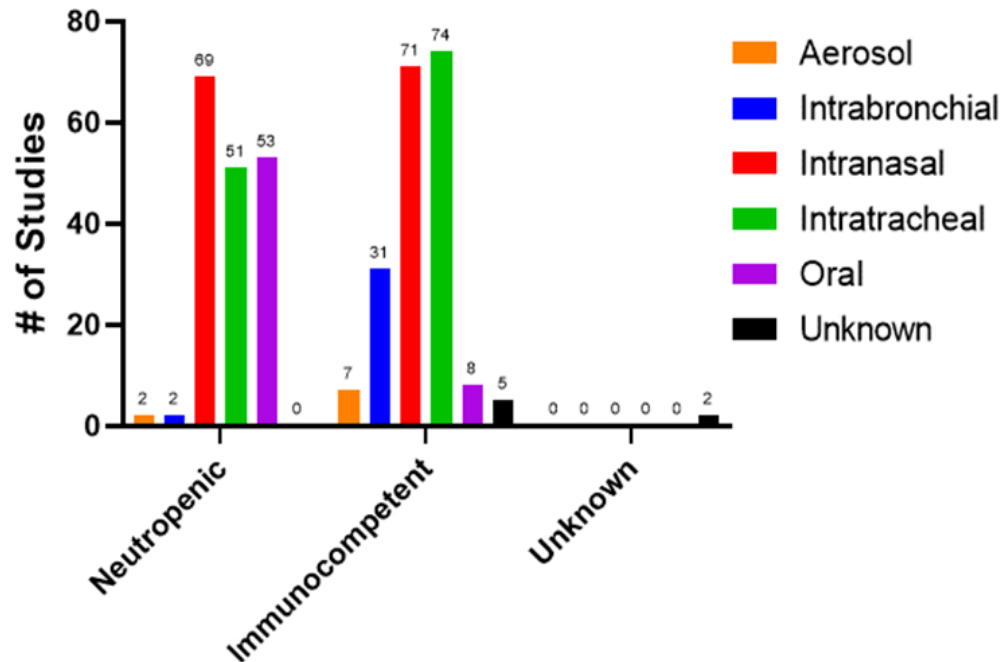
# Similar Use of Neutropenic and Immunocompetent Models



IND Database



Published Literature Database



# Conclusions

- Study designs are highly variable
  - Opportunity for harmonization
- IND database and Published Literature database are distinct datasets that show similar trends
  - Surprisingly, little overlap exists between the databases

# Conclusions, continued

- Both neutropenic and immunocompetent animals were used in models
- Studies with neutropenic mice inoculated intranasally were most common
- Mice were utilized for short term studies (<48 hours), larger animals for longer term studies (>48 hours)

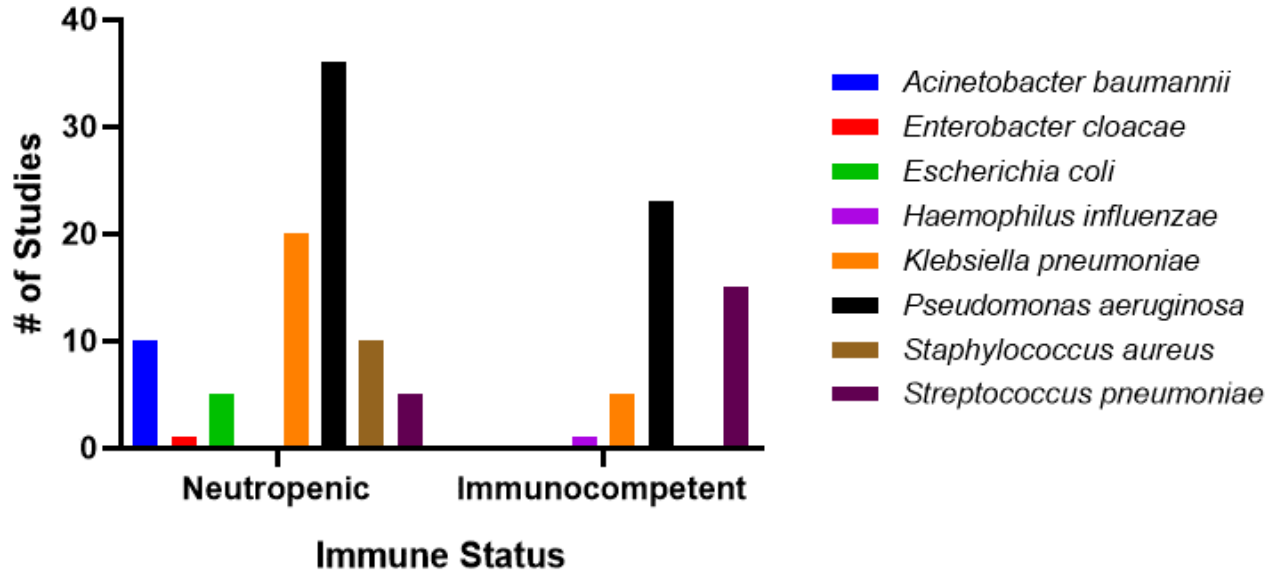
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# Similar use of Neutropenic and Immunocompetent Mice for Predominant Bacteria in INDs



# Similar use of Neutropenic and Immunocompetent Mice for Predominant Bacteria in Published Literature

